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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
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08/507,863 07/27/95 GREFF

R 018413-002

EXAMINER
NILAND, P

15M1/0801

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ART UNIT PAPER NUMBER

1511
DATE MAILED:

08/01/96

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 5/16/96

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-15 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-15 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) (2 sheets)

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

- SEE OFFICE ACTION ON THE FOLLOWING PAGES -

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15. The amendment of 5/16/96 has been entered. Claims 1-15 are pending.

16. The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

17. Claims 1-15 are rejected under 35 U.S.C. § 103 as being unpatentable over US Pat. No. 5443454 Tanabe et al. in view of Taki, "Possibility and Limit of Intravascular Surgery", Medical Tribune, October 26, 1989, Pages 46-47, US Pat. No. 4795741 Leshchiner et al., US Pat. No. 5202352 Okada et al., and US Pat. No. 4079124 Winchell.

Tanabe et al. and Taki disclose the use of a composition of 5% ethylene vinyl alcohol copolymer and 100 ml of DMSO which falls within the scope of the instantly claimed ingredients (a) and (c) of the instant claims 1-3 and 7-9. The ethylene vinyl alcohol copolymer is 33 mole % ethylene and therefore 67 mole % vinyl alcohol, which falls within the scope of the instant claims 2 and 8.

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See column 2, lines 7-13 and 42-51; column 11, lines 13-49; and column 12, lines 13-50 of Tanabe et al.. Tanabe et al. discloses adding X-ray contrast medium to the embolic material but is silent as to the identities of the contrasting materials. See column 11, lines 50-53. It would have been obvious to one of ordinary skill in the art at the time of the instant invention to use tantalum, tantalum oxide, or barium sulfate as the X-ray contrast agent of Tanabe et al. , in the instantly claimed amounts, because Leshchiner et al. discloses the use of powdered tantalum and barium sulfate in embolizing compositions as X-ray contrast agents at column 3, lines 36-47, in amounts falling within the amounts of the instant claims, Winchell discloses tantalum oxide as an X-ray contrasting agent which is biocompatible at column 3, lines 1-35 and column 6, lines 41-58, Okada et al. recognizes the surfactant ability of polyvinyl alcohol compounds at column 9, lines 7-9, the surfactant ability of the polyvinyl alcohol copolymer and the viscosity of the solution of copolymer of Tanabe et al. are expected to maintain the X-ray contrasting agents of Leschiner et al. in a dispersed state just as pigment is typically dispersed in solvent based paints or spinning solutions of polymer, and the X-ray contrast agents of Leshchiner et al. are expected to provide the surgeon the ability to see the embolized area with X-rays, as specified by Tanabe et al.. The applicant provides no unexpected results which are commensurate in scope with the cited prior art and the instantly encompassed ingredient amounts, polymer molecular weights, vinyl alcohol to ethylene ratios, contrasting agent particle sizes, and other physical characteristics

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encompassed by the instant claims and the cited prior art which materially affect the instantly claimed composition's properties.

The embolizing method steps described by Tanabe et al. fall within the scope of the method steps of the instant claims 7-12. The patentee is silent as to the injection rates of the instant claims 13-15. Tanabe et al. does disclose the formation of filaments, which falls within the scope of the instant claim 15. It would have been obvious to one of ordinary skill in the art at the time of the instant invention to inject the embolizing solution discussed above by the method according to Tanabe et al. at the injection rates of the instant claims 13-15 because the choice of such injection rates is within the ability of the ordinary skilled artisan, i.e. the surgeon, as evidenced by the patentee's silence as to the choice of injection rates, the injection rate influences whether or not the spinning orifice clogs up, defining a minimum injection rate usable, and whether or not the blood vessel bursts in extreme cases and more routinely whether or not the extruded filaments shoot past the site at which they are desired to embolize. The applicant has demonstrated no unexpected results for the injection rates of the instant claims 13-15 in a manner which is commensurate in scope with the cited prior art and the instant claims.

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The applicant argues "The compositions of this invention are particularly suited for embolization of blood vessel and, surprisingly, these compositions are easily delivered to the vascular site and rapidly form a coherent solid material which encapsulates or entraps the water insoluble contrast agent..". It is the examiner's position that this is not unexpected. As stated above, Tanabe et al. discloses the use of a contrasting material generally in the polymer/solvent medium and its delivery to a vascular site and the other secondary references show the instantly claimed contrasting agents to be known as biocompatible contrasting agents. The general statement of the use of contrasting agents at column 11, lines 50-53 of Tanabe et al. provides the requisite motivation to use the known contrasting agents of the secondary references, contrary to the applicant's arguments otherwise. It is expected that the water insoluble contrasting agent, which is a pigment in fact, would have been encapsulated by the polymer because this is the well known final structural relationship of binder and pigment of pigmented binders in similar compositions such as pigmented paints and pigmented fiber spinning solutions. One only needs to examine pigmented films and fibers which existed prior to this invention to see that this is so. In such compositions of film forming polymer, solvent, and pigment, the pigment is always encapsulated by the polymer and the adhesive nature and film forming nature of the polymer cause the pigment to be encapsulated within the polymer. The ordinary skilled artisan would have expected the same physics to occur in the instant compositions and methods, i.e. the dissolved ethylene

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vinyl alcohol copolymer is capable of forming film by its polymeric nature and is therefore expected to be able coat the particles of the contrasting agent with polymer due to its low viscosity, dilute nature when dissolved, just like any other polymer solution, such as paint, will coat harder, insoluble particles, just as paint binder coats pigment. Tanabe et al. shows that fibers are formed from their solution, which are the "coherent solid material[s]" of the applicant's arguments. As discussed above, the contrasting agent would have been expected to have been encapsulated within the polymer of Tanabe et al. and therefore would not have been expected to be a non-coherent mass. The applicant argues that example 3 demonstrates unexpected results. Comparisons with water soluble contrasting agents are not persuasive because where the soluble material is in water the low amount of somewhat hydrophilic (due to the vinyl alcohol segments) polymer will be water swellable allowing the soluble material to dissolve into small molecules which can easily escape from the low amount of swollen binder. Where insoluble contrasting agent is used, the contrasting agent will clearly be unaffected by the water and therefore the low amount of polymer binder and any swellability of the binder would not have been expected to allow the contrasting agent to escape. Note that when it rains the pigment in house paint does not dissolve away. It is therefore the examiner's position that the results of the applicant's example 3 are not unexpected. The examiner's rationale and tests for obviousness meet all of the requisite criteria and

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are technologically correct. The applicant's arguments directed to caselaw are therefore not persuasive. The applicant's arguments have been fully considered but are not persuasive for the reasons stated above. This rejection is therefore maintained.

18. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Niland on Monday to Friday from 9:30 to 6:00 whose telephone number is (703) 308-3510. If the examiner cannot be reached and the inquiry is urgent, call Paul Michl at (703) 308-2451. Direct any faxes to members of Art Unit 1511 to (703) 305-5433.


pn

July 30, 1996

Serial Number: 08/507863

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PAUL R. MICHL
SUPERVISORY PATENT EXAMINER
ART UNIT 156